

**REMARKS**

This amendment is submitted in response to the Final Office Action mailed May 6, 2008, in connection with the above-identified application (hereinafter, the "Office Action"). The Office Action provided a three-month shortened statutory period in which to respond, ending on August 6, 2008. Accordingly, this amendment is timely submitted.

**I. Pending Claims**

Claims 22, 24-28, 30, 32-33 and 35-37, of which claims 22 and 30 are independent, remain pending and appear in this application for the Examiner's review and consideration. Claim 22 has been amended by incorporating the recited features of claim 23, thereby cancelling claim 23. In addition, claims 23 and 30 are amended to recite particular viscous soluble fibers and that the viscosity-lowering protein(s) has the ability to lower the viscosity of the composition to less than about 500 mPas at room temperature. Claims 23-28 and 32-37 have been amended to correct minor clerical errors and provide clarity to the claims. Claims 1-8, 23, 31, 34 and 42-43 have been cancelled. Claims 19-21, 29, 38-41 and 44-51 have been withdrawn. Claims 52-55 have been added, to more particularly point out and distinctly claim that which Applicant regards as the invention under 35 U.S.C. §112, second paragraph. No new matter is believed added.

Claims 48 and 50-51, directed to methods of using the claimed compositions, remain withdrawn, but it is understood that these claims will be rejoined when the pending composition claims are allowed. As to the cancelled claims and to the extent that the withdrawn claims are not rejoined, Applicant reserves the right to pursue these claims in a divisional or continuation application. Applicant respectfully submits that no new matter has been introduced by these amendments. Therefore, they all amendments should be entered at this time.

Applicant does not acquiesce in the correctness of the rejections or objections, and reserve the right to present specific arguments regarding any rejected or objected-to claims not specifically addressed. Further, Applicant reserves the right to pursue the full scope of the subject matter of the claims in a subsequent patent application that claims priority to the instant application.

Applicant respectfully submits that the objections and rejections based on indefiniteness, lack of novelty and obviousness are overcome in view of the amendments and arguments presented in the response. Applicant, therefore, respectfully requests that all amendments be entered at this time and reconsideration of this application in view of the above amendments and the following remarks presented hereinbelow.

## **II. Rejection Under 35 U.S.C §112, Second Paragraph**

The Office Action contended that the claim phrase "about 500 mPas" may be "broadly and reasonably" interpreted as to embrace "a broad range of viscosities, including compositions with viscosities orders of magnitude above 500 mPas." Applicant, however, respectfully submits that the claims are not ambiguous with the inclusion of the phrase "about 500 mPas" because one of skill in the art, upon reading the specification, well understands the meaning of this phrase and the extents of claim coverage are not indefinite." In fact, the specification does provide examples of when a viscosity is less than "about 500 mPas," e.g., less than about 250 mPas or less than about 150 mPas, less than about 100 mPas or less than about 60 mPas. Support is found in the published patent application, US2006/0099324A1, along with sufficient context to properly delineate the invention. Page 1, paragraph [0015], lines 10-15, for example.

In view of the above remarks, Applicant respectfully submits that the phrase is not indefinite. Withdrawal of this rejection is, accordingly, earnestly requested.

## **III. Rejection Under 35 U.S.C §102(b)**

Claims 22, 26-28, 30 and 35-37 have been rejected under 35 U.S.C. §102(b), as being anticipated by U.S. Patent No. 6,210,686 to Bell et al. (referred hereinafter as "Bell"). Applicant respectfully disagrees with the rejection. At the outset, the claimed compositions, as set forth in amended independent claims 22 and 30, as well as the claims that depend therefrom, require the following features: (1) that composition should include one or more viscous soluble fiber(s) and one or more viscosity-lowering protein(s); (2) one or more of the viscous soluble fiber(s) may be an agar, alginates, a carubin, a pectin, a beta-glucan, carrageenan, a furcellaran, an arabinogalactan, a pectin and its derivatives, a cellulose and its derivatives, a scleroglucan, psylliums and gums; (3) one or more viscosity-lowering protein(s) are moderately hydrolyzed and can be a wheat protein, an egg

protein, a collagen, a whey protein, a casein, a soy protein, a pea protein, a muscle protein, gluten, a fibrillar protein, a silk protein and combinations thereof; and (4) wherein one or more viscosity-lowering protein(s) has the ability to lower the viscosity of viscous soluble fibers in the composition to less than about 500 mPas at room temperature. Support for the amendments are set forth in the published patent application at page 1, paragraph [0005] and [0016] and page 2, paragraph [0019].

Contrary to the claimed invention, Bell generally describes dietary supplements that include yeast-derived fiber, e.g., glucan, or glucomannan, folic acid or a salt thereof, vitamin B<sub>6</sub>, vitamin B<sub>12</sub> and vitamin E. The dietary supplements further include fats, carbohydrates, and proteins. Bell's dietary supplements are for lowering the risk of heart disease and for improving cardiovascular health in humans. See, Bell's abstract. Bell's dietary supplements, however, fail to include all the required features of the claimed invention, particularly, the ability of the viscosity-lowering protein to lower the viscosity of the viscous soluble fiber in the composition. Indeed, Bell's dietary supplements are entirely different from that of the claimed composition, and are patentably distinct therefrom. Accordingly, Applicant respectfully submits that Bell fails to anticipate the claimed compositions and fails to render them obvious. Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejection.

Claims 22, 23, 26-28, 30 and 35-37 have been rejected under 35 U.S.C. §102(b), as being anticipated by Australian Patent Application No. AU 9873118 A to Jaussan et al. (referred hereinafter as "Jaussan"). Jaussan generally describes a nutritional composition for diabetic patients that includes a protein source, a lipid source, a carbohydrate source and a fiber mixture that includes a viscous soluble fiber and inulin, a hydrolysate of insulin or both. The goal of Jaussan's composition is to increase the viscosity of the contents of the stomach and the small intestine. This is directly contrary to the purpose of the claimed composition, i.e., to provide a non-viscous composition that can be enterally or orally administered to a human. As pointed out in the specification, high viscosity may render problematic the preparation of a composition for oral or enteral administration. See published patent application, at page 1, paragraph [0004]. In addition, the claimed compositions do not require inulin or its hydrolysates. Jaussan, like Bell, also fails to describe or suggest all the recited features of the claimed compositions. Accordingly, Applicant respectfully submits that Jaussan fails to anticipate the claimed

compositions, as set forth in amended claims 22 and 30, as well as the claims that depend therefrom. Reconsideration and withdrawal of the rejection are earnestly requested.

Claims 22, 25-27, 30, 33, 35 and 36 have been rejected under 35 U.S.C. §102(b), as being anticipated by U.S. Patent No. 6,589,511 to Shimizu (referred hereinafter as "Shimizu"). Shimizu generally describes a composition for forming solid particles that include a biodegradable polymer, a solvent, a polyhydric alcohol, a viscosity increasing agent and an active drug; wherein the composition is in form of an emulsion. Shimizu's composition can be used in the treatment of or as a prophylactic for periodontal disease or gingivitis. Like Bell and Jaussan, however, Shimizu also fails to disclose or suggest all the features of the presently-claimed compositions. In particular, Shimizu's composition increases the viscosity instead of lowering it, as required by the claimed compositions. In addition, Shimizu fails to disclose each and every element of the present claims. Thus, Shimizu, like Bell and Jaussan, fails to both anticipate and render obvious the present invention, as claimed. In view of the amendments and remarks presented herein, reconsideration and withdrawal of the rejection in view of Shimizu are respectfully requested.

Claims 22, 25-27, 30, 33, 35 and 36 have been rejected under 35 U.S.C. §102(b), as being anticipated by U.S. Patent No. 5,470,839 to Laughlin et al. (referred hereinafter as "Laughlin"). Applicant respectfully disagrees with the rejection. Laughlin generally describes a composition and method for providing a nutrition to a diabetic patient, wherein the composition is a low carbohydrate and a high fat formulation (particularly medium chain triglycerides). See, Laughlin's Abstract. The composition may further include a protein source (e.g., casein, whey protein, or non-fat milk) and a dietary fiber. Laughlin, at column 5, lines 29-32, and column 5, lines 62-67. Like the above-cited primary references, Laughlin also fails to disclose or suggest every element of the present invention, as claimed. Laughlin's composition utterly fails to include one or more moderately-hydrolyzed viscosity-lowering protein(s) that is capable of lowering the viscosity of the viscous soluble fibers in the composition before it is orally or enterally administered to the diabetic subjects. Accordingly, Applicant again respectfully requests the reconsideration and withdrawal of the rejection.

Claims 22-28, 30, 32, 33 and 35-37 are rejected under 35 U.S.C §102(b) as being anticipated by European Patent Application No. 0323510 A1 to Ohta et al. (referred hereinafter

as "Ohta"). Ohta generally describes a food composition which includes water-soluble edible fibers (e.g., carageenan and guar gum) and proteins (e.g., casein or its salts) having isoelectric point in an acidic region in such a content that an aqueous solution of the composition gels when in contact with the gastric juice. See Ohta's Abstract. Ohta's compositions are useful as food for preventing rapid increase in blood glucose level in patients with glucose intolerance, e.g., diabetic mellitus patients. The Office Action cited Figure 1 in the Ohta reference and asserted that "Ohta also teaches modifying the pH and temperature to affect viscosity, including effecting a viscosity below 100 cPs, including less than 50 cPs (Figure 1)." Office Action, at page 5. However, Figure 1 of Ohta shows the effects of the 1N HCl on the viscosity of precooked corn potage soup at 40°C (mimicking the temperature of the stomach). As shown, the temperature reduction (70°C→40°C) lowers the viscosity of the soup. See, Ohta at page 6, last full paragraph — page 7, first and second full paragraphs. According to Ohta, the correlated reduction of viscosity and pH of the gastric juice in the stomach is viewed unfavorably from retention time in the stomach. Ohta goes on to state the contrary to the data observed in Figure 1, the food composition according to his invention resulted to an increased viscosity by reduction in temperature. In contrast to Ohta's claimed food composition, the object of the presently-claimed invention is to decrease the viscosity of the viscous soluble fiber in the compositions before being administered orally or enterally to the patient's stomach. This is achieved by the use of one or more viscosity-lowering proteins that are moderately hydrolyzed. Ohta utterly fails to describe and let alone suggest this important feature of the present invention, as claimed and set forth in amended claims 22 and 30, as well as the claims that depend therefrom. In view of the remarks and amendments presented herein, Applicant respectfully submits that Ohta fails to teach each and every feature of the claimed invention, and, therefore, the claimed compositions are patentable over Ohta. Accordingly, reconsideration and withdrawal of the rejection over of Ohta are earnestly requested.

Claims 22, 26-28, 30 and 35-37 are rejected under 35 U.S.C § 102(b) as being anticipated by U.K. Patent Application No. 2021948 A to Heath et al. (referred hereinafter as "Heath"). Heath generally describes the use of gums in therapy for the reduction of cholesterol and/or glucose level in the blood. Examples of gum include guar gum, pectin, locust bean gum and alkyl celluloses. The fine particles of the gum are coated with a layer of substance (e.g., protein) having a tendency to absorb water than the gum. See, Heath's Abstract. However, Applicant

respectfully submits that Heath's water-miscible gum compositions are different from the claimed invention. Heath fails to disclose a composition that has a viscosity lower than 500 mPas and wherein the weight ratio of the fiber to the protein about 0.01:1 to about 20:1. But, more specifically, Heath's composition fails to include moderately hydrolyzed viscosity-lowering protein(s) that are capable of lowering the viscosity of the viscous soluble fibers in the composition before it is orally or enterally administered. Thus, in view of the remarks and claim amendments, Applicant respectfully submits that Heath's compositions do not anticipate the claimed compositions. Because Heath fails to disclose and suggest each and every element of the present invention, as presently-claimed herein, Applicant respectfully requests the reconsideration and withdrawal of the claim rejection.

Lastly, Claims 22-28, 30, 32, 33 and 35-37 are rejected under 35 U.S.C §102(b) as being anticipated by U.S. Patent No. 6,355,609 to Mallangi et al. (referred hereinafter as "Mallangi"). Mallangi generally describes nutritional solutions (e.g., enteral) and methods of making such solutions that include protein, lipid, a carbohydrate source including high amylase starch and guar gum. See, Mallangi's Abstract. According to Mallangi, stability of the nutritional solutions can be improved by providing a stabilizing combination of starch and gum (Mallangi, at column 3, lines 47-67), and that addition of guar gum or Carageenan to a starch formula would increase viscosity (Mallangi, at column 6, lines 59-65). This is contrary to the claimed composition, wherein one or more moderately hydrolyzed viscosity-lowering proteins are added to lower the viscosity of the viscous soluble fibers in the composition prior its oral or enteral administration to a subject. In view of the claim amendments and remarks presented herein, Mallangi, as with the other references, fails to describe or even suggest every feature of the claimed compositions, as set forth in amended claims 22 and 30. Thus, claims 22-28, 30, 32, 33 and 35-37 are patentable over Mallangi. Reconsideration and withdrawal of the rejection are respectfully requested.

Applicant respectfully requests that all of the §102 rejections be reconsidered and withdrawn at least in view of the arguments and claim amendments set forth hereinabove, and further in view of additional arguments hereinbelow.

#### **IV. Rejection Under 35 U.S.C §103(a)**

Claims 22-28, 30, 32, 33 and 35-37 are rejected under 35 U.S.C §103(a) as being unpatentable for obviousness over U.S. Patent No. 6,287,623 to Nakayama et al. (referred hereinafter as "Nakayama"). Applicant respectfully disagrees with the rejection.

The above arguments presented to overcome the Examiner's anticipation rejection based on all the cited primary references are incorporated herein.

Nakayama generally describes a method for producing a protein-containing acid food and drink that includes a protein emulsion having a pH value that is higher than the isoelectric point of the protein in the emulsion at high temperature to make the emulsion having a pH value that is lower than the isoelectric point of the protein. Examples of proteins include soybean protein, wheat protein, plasma or blood cell protein, collagen etc. However, examples of a viscous soluble fiber are not provided, except agar, as provided in Example 8 of Nakayama. Applicant respectfully submits that Nakayama, as with the other references, fails to describe or suggest compositions that include one or more viscosity-lowering protein(s) that is moderately hydrolyzed and capable of lowering the viscosity of the viscous soluble fibers in the composition before it is orally or enterally administered to a subject, as set forth in the present claims. Thus, Nakayama fails to describe or suggest all the elements of the claimed invention. Accordingly, Applicant respectfully requests that the §103(a) obviousness rejection be reconsidered and the rejection be withdrawn.

Applicant respectfully submits that the present invention, as claimed herein, is neither anticipated by nor rendered obvious in view of the Bell, Jaussan, Ohta, Heath, Shimizu, Mallangi and Nakayama references. Reconsideration and withdrawal of the § 102(a) and 103(a) rejections are respectfully requested.

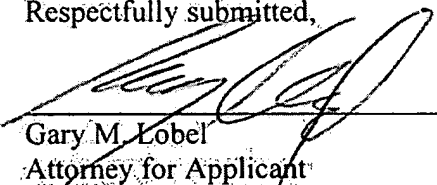
**CONCLUSION**

For at least the reasons set forth above, Applicant respectfully submits that this application is in condition for allowance. Favorable consideration and prompt allowance of the claims are earnestly requested. Should the Examiner have any questions that would facilitate further prosecution or allowance of this application, the Examiner is invited to contact the Applicant's representative designated below.

The Commissioner is hereby authorized to charge any additional fees under 37 CFR §1.17 which may be required, or credit any overpayment, to deposit account no. 50-4498 in the name of Nestle Nutrition.

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Respectfully submitted,



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